

### **REMARKS**

Claims 46-65 are pending in the present application. Claims 46, 55, and 56 have been amended to clarify that which Applicants regard as the invention. Specifically, claims 46 and 55 have been amended to recite specific non-ionic surfactants. Support for this amendment can be found in the specification, for example, at page 13, lines 26-27 and page 25, lines 24-27. Claim 56 has been amended to recite that the excipient is a Polysorbate. Support for this amendment can be found in the specification, for example, at page 11, lines 1-6 and page 25, lines 24-27. These amendments are presented solely to expedite prosecution. Applicants reserve the right to pursue the subject matter of the originally filed claims at a later date. Claims 46, 49, 51, and 55-59 have been amended to correct typographical errors. Specifically, claim 46 has been amended to insert a missing hyphen in  $\beta$ -cyclodextrin. Support for this amendment can be found in the specification, for example, at page 16, line 6. Claim 49 has been amended to delete duplication of the term "QS-21." Claim 51 has been amended to contain the proper language of a Markush group. Claims 55-59 have been amended to be directed to methods instead of compositions. Support for this amendment can be found in the specification, for example, at page 10, lines 31-32, page 11, lines 1-17 and 30-32, page 13, lines 25-32, page 16, line 6, and page 19, lines 29-32. No new matter has been added by these amendments. Upon entry of this amendment, claims 46-65 will remain pending in the present application.

Applicant respectfully requests that the amendments and remarks made herein be entered and fully considered.

### **Restriction**

The Examiner has required an election under 35 U.S.C. § 121 of one of the following inventions:

- I. Claims 46-54 and 60-65, drawn to a method of enhancing the immune response to an antigen, classified in Class 424, subclass 184.1.
- II. Claims 55-59, drawn to a composition of excipient, classified in Class 424, subclass 193.1.

The Examiner contends that Group I and II are related as product and process of using. Applicants respectfully traverse the Restriction Requirement.

In response to the Restriction Requirement, Applicants have amended claims 55-59 to be drawn to methods of enhancing the immune response to an antigen. Thus,

Applicants respectfully request that the restriction requirement be reconsidered and that the claims of Group I and the claims of Group II be grouped together.

However, in order to be fully responsive, Applicants hereby elect the invention of Group I, claims 46-54 and 60-65, directed to methods of enhancing the immune response to an antigen, classified in Class 424, subclass 184.1, with traverse.

**Species Election**

The Examiner additionally requires that upon election of Group I or Group II, a further election be made of a particular form of the excipient from the following:

- a.  $\beta$  cyclodextrin,
- b. human serum albumin,
- c. deacylsaponin,
- d. non-ionic surfactant,
- e. polyvinylpyrrolidone (Plasdone C15),
- f. aluminum hydroxide,
- g. agent with anesthetic action, or
- h. unmodified or derivative of cyclodextrin.

If Applicants elect non-ionic surfactant, the Examiner further requires election of an ultimate species of non-ionic surfactant, *e.g.*, Polysorbate 20.

In response, Applicants hereby elect, with traverse, non-ionic surfactant, and the ultimate species of Polysorbate 20. Applicants believe that claims 46-57 and 63-65 are readable upon this elected species.

Applicants respectfully traverse the Examiner's requirement for election of species and request that the requirement be withdrawn.

Applicants submit that to search the subject matter of the individual species in claim 46 (*i.e.*, a  $\beta$  cyclodextrin, a human serum albumin, a deacylsaponin, a Polysorbate and Triton X-100) together would not be a serious burden on the Examiner. Applicants assert that, pursuant to MPEP § 803.02, the subject matter of the individual species can be examined together in a single application without imposing a serious burden to the Examiner. The M.P.E.P. § 803 (Eighth Edition, Revision 2, May 2004) states:

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Alternatively, a search of Polysorbates (*i.e.*, Polysorbate 20, Polysorbate 40, Polysorbate 60, and Polysorbate 80) involves a group sufficiently few in number and so closely related (Polysorbates are esters of sorbitol and its anhydrides condensed with polymers of ethylene oxide) that a search and examination of the entire group would not be a serious burden on the Examiner. See *id.*, § 803.02.

Applicants submit therefore, that according to MPEP §§ 803 and 803.02, claims 46-65 should be examined together, because the search and examination of these claims would not unduly burden the Examiner.

Accordingly, Applicants respectfully request that the requirement for species election be withdrawn, or alternatively, that the species election include all Polysorbates.

The Examiner additionally requires that upon election of Group I or Group II, a further election be made of a particular antigen from the following:

- a. peptide,
- b. protein,
- c. polysaccharide,
- d. lipid,
- e. nucleic acid,
- f. virus, or
- g. bacteria.

If Applicants elect a virus or bacteria, the Examiner further requires election of an ultimate species of viral or bacteria antigen.

In response, Applicants hereby elect, with traverse, protein. Applicants believe that claims 46-65 are readable upon this elected species.

Applicants respectfully traverse the Examiner's requirement for election of species and request that the requirement be withdrawn.

Applicants submit that to search the subject matter of the individual species together would not be a serious burden on the Examiner. Applicants assert that, pursuant to MPEP § 803.02, the subject matter of the individual species can be examined together in a single application without imposing a serious burden to the Examiner. See M.P.E.P. § 803.

Alternatively, Applicants respectfully submit that peptides and proteins are so closely related, both being polymers of amino acids, that a search and examination of these two species would not be a serious burden on the Examiner. See *id.*, § 803.02. Moreover, in

the context of an antigen, these terms are closely related as a protein antigen will comprise antigenic peptides.

Applicants submit therefore, that according to MPEP §§ 803 and 803.02, claims 46-65 should be examined together, because the search and examination of these claims would not unduly burden the Examiner.

Accordingly, Applicants respectfully request that the requirement for species election be withdrawn, or alternatively, that the species election include both peptides and proteins.

Attorneys for Applicants retain the right to petition from the restriction requirement under 37 U.S.C. § 1.144.

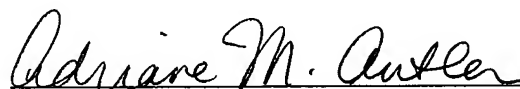
Should the species restriction be maintained, Applicants, upon the allowance of a generic claim, will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim pursuant to 37 C.F.R. § 1.141.

#### **CONCLUSION**

Applicants respectfully request that the present amendments and remarks be made of record in the instant application. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

Respectfully submitted,

Date: November 19, 2004

 32,605  
Adriane M. Antler (Reg. No.)  
**JONES DAY**  
222 East 41<sup>st</sup> Street  
New York, NY 10017  
(212) 326-3939